The Tides of Change: Implementing Early Onset Psychosis Services with a National Thought Leader

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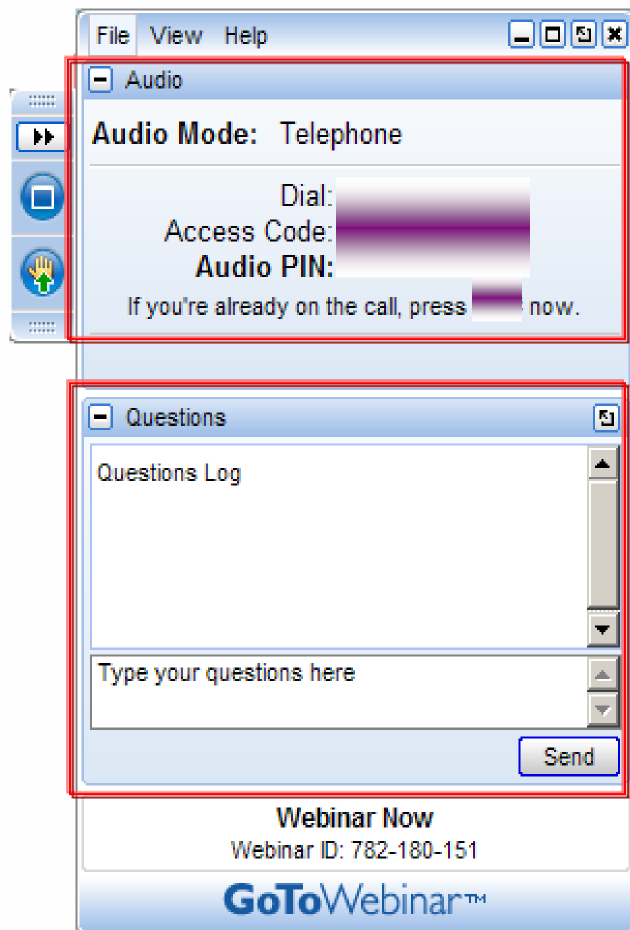
John M. Kane Disclosures 2015

Dr. Kane has been a consultant for Alkermes, Eli Lilly, EnVivo Pharmaceuticals (Forum), Forest, Genentech, H. Lundbeck. Intracellular Therapeutics, Janssen Pharmaceutica, Johnson and Johnson, Otsuka, Reviva, Roche, Sunovion and Teva.

Dr. Kane has received honoraria for lectures from Janssen, Genentech, Lundbeck and Otsuka

Dr. Kane is a Shareholder in MedAvante, Inc. and Vanguard Research Group

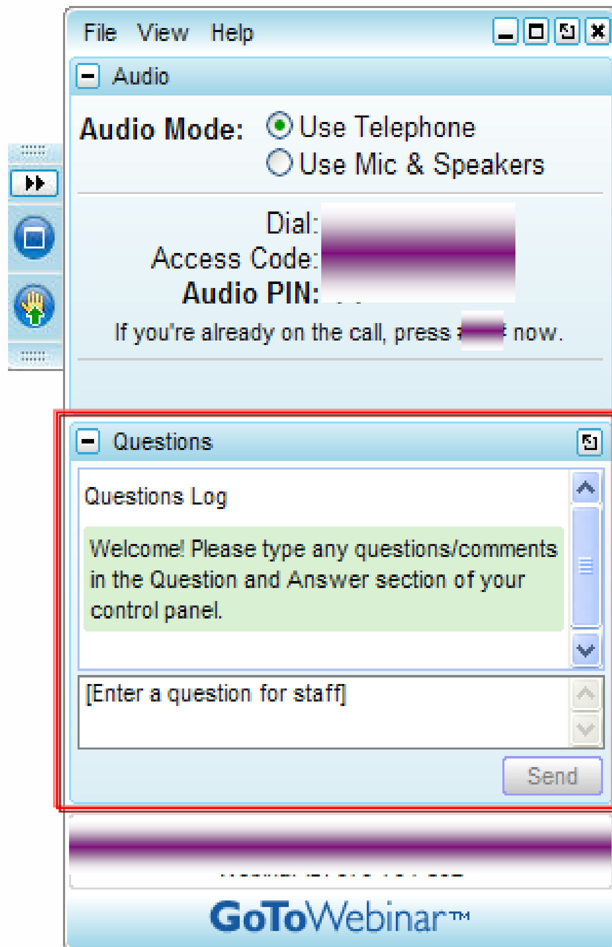
Housekeeping



How to participate

- Your unique audio pin is located in the Audio Pane. See example.
- Submit your text question using the Questions pane
- **Note:** A copy of this presentation and the recording will be make available within 48 hours

Thank you for participating



Time for Questions

- Submit your text questions now using the Webinar Questions pane
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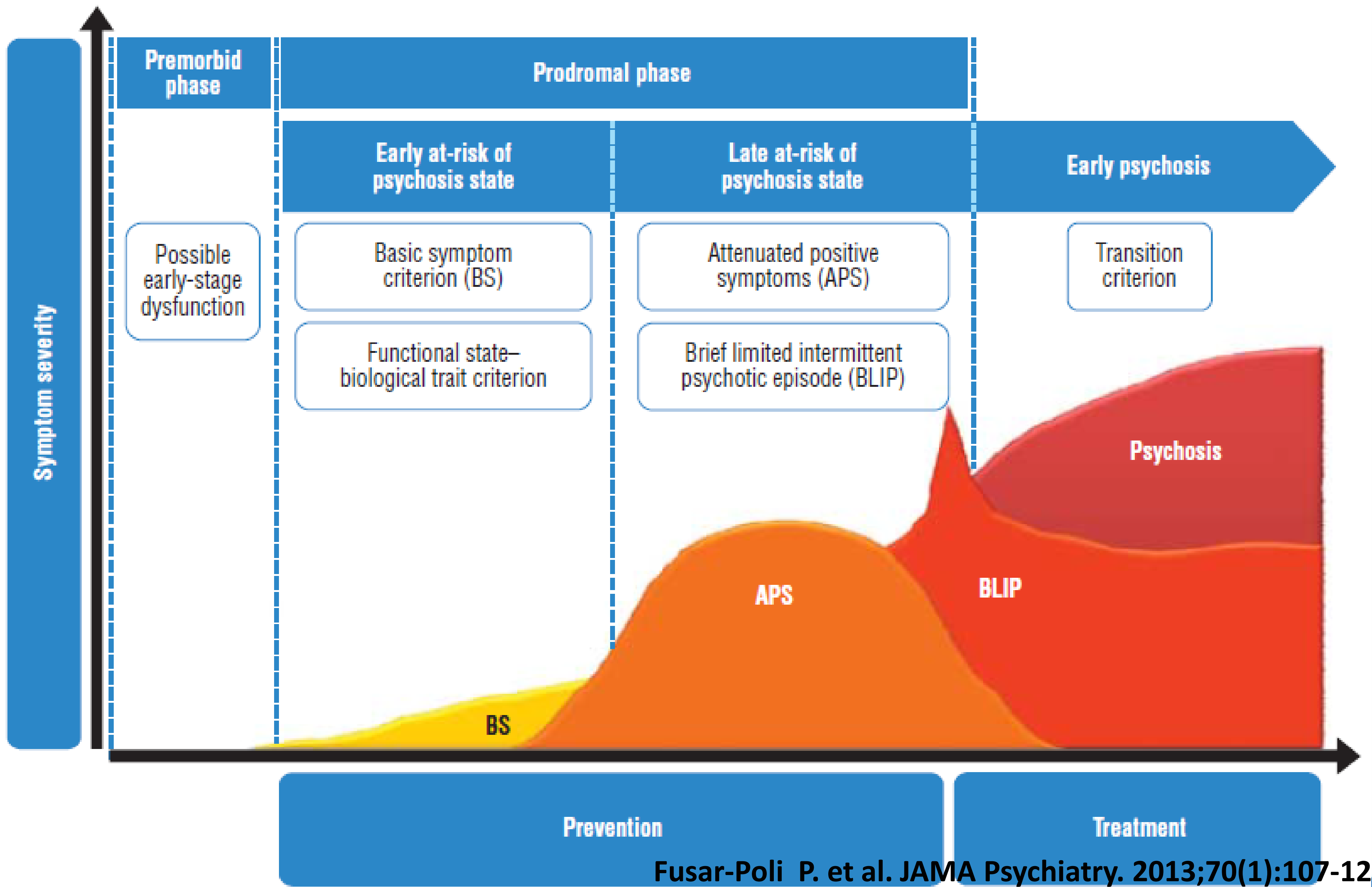
Evolution of Psychosis



Fusar-Poli P. et al. JAMA Psychiatry. 2013;70(1):107-120.

Clinical Characteristics of First-episode Psychosis

- Typically adolescent or young adult
- Have lived with severe untreated psychotic symptoms
  - On average, for at least a year
- Compared to peers
  - Cognitively impaired
  - Poorer psychosocial functioning
  - More likely to smoke
  - More likely to abuse substances
- Families are typically actively engaged
- Goals are to return to mainstream functioning

Reported Mean Duration of Untreated Psychosis

1 year

Wiersma 2000
Amminger 2002**
Malla 2002
Linszen 2001
Verdoux 2001
Black 2001
Larsen 2000
Hoff 2000
Ho 2000
Drake 2000
Browne 2000
Barnes 2000
Robinson 1999*
McGorry 1996**
Larsen 1996
Szymanski 1996
Loebel 1992*

0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180

Weeks

Presented by Diana O. Perkins, MD, MPH. University of North Carolina at Chapel Hill, 26th Sept 2003 (available at: www.medscape.org/viewarticle/460974)

Implications of Delayed Treatment

- Greater decrease in functioning
- Loss of educational opportunities
- Impaired psychosocial and vocational development
- Personal suffering/family burdens
- Potential poorer response once treatment is provided
- Greater costs

UCLA Recovery Criteria

- Recovery criteria must be met in each of 4 domains
- Improvement in each domain must be sustained concurrently for ≥2 years
- Level of recovery in these 4 domains is measured by symptom remission, appropriate role function, ability to perform day-to-day living tasks without supervision, and social interactions

Liberman et al. Int Rev Psychiatry 2002;14:256–272

Cumulative Recovery Rates by Year in Study

Year	Cumulative recovery rate (%)	95% CI	
		Lower limit	Upper limit
3	9.7	3.7	15.8
4	12.3	5.4	19.1
5	13.7	6.4	20.9

CI=confidence interval
Robinson et al. Am J Psychiatry 2004;161(3):473–479

A Systematic Review and Meta-analysis of Recovery in Schizophrenia

Erika Jääskeläinen*[1,6], Pauliina Juola[1], Noora Hirvonen[1,2], John J. McGrath[3,4], Sukanta Saha[3], Matti Isohanni[1], Juha Veijola[1], and Jouko Miettunen[1,5,6]

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[6]These authors contributed equally to the article.

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Conclusions:

Based on the best available data, approximately, 1 in 7 individuals with schizophrenia met our criteria for recovery. Despite major changes in treatment options in recent decades, the proportion of recovered cases has not increased

Jääskeläinen et al. Schizophr Bull 2013;39(6):1296–1306

Recovery After an Initial Schizophrenia Episode

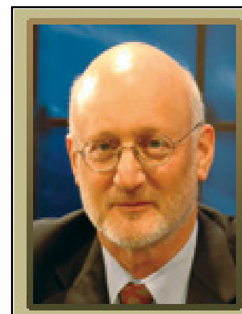
RA1SE

A Research Project of the NIMH

Early Treatment Program

RAISE-ETP: Executive Committee

John Kane – Principle Investigator	**The Zucker Hillside Hospital (ZHH)**
Delbert Robinson	ZHH
Nina Schooler	SUNY Downstate
Jean Addington	University of Calgary
Christoph Correll	ZHH
Sue Estroff	UNC
Kim Mueser	Boston University
David Penn	UNC
Robert Rosenheck	Yale University
Mary Brunette	Dartmouth University
Jim Robinson	Nathan Kline Institute
Patricia Marcy	ZHH – Project Director



- Key Consultants:
  - Tom Tenhave and Andy Leon assisted in designing the trial.
  - Robert Gibbons, Don Hedeker and Hendricks Brown reviewed the data analytic plan.
  - Haiqun Lin led the analysis.

PRINCIPAL NIMH COLLABORATORS

Robert Heinssen
Susan Azrin
Amy Goldstein

The Problem of First Episode Psychosis

- Poor recognition
- Longer duration of untreated psychosis related to worse outcomes
- Lack of youth-friendly, patient-centered treatment
- Inadequate psychoeducation and family involvement
- High rates of medication non-adherence
- High rates of dropout from treatment

Specified Aims of RAISE

1. Develop an integrated treatment model for First Episode Psychosis (FEP) that
   - maximizes functioning
   - promotes symptomatic recovery
   - can be brought to scale

2. Compare the intervention to prevailing treatment approaches for FEP

3. Conduct the study in non-academic, U.S. community treatment settings

NAVIGATE Intervention

- Overall goal is recovery, not maintenance
- Team-based, multi-component intervention
- Shared decision-making to insure client and family involvement in treatment planning and execution
- Training and on-going consultation to insure fidelity
- Services supported through current reimbursement mechanisms

NAVIGATE Components

Provider	Component
Program Director	Establish referral networks, speed enrollment, assure team cohesion
Physician/Nurse Practitioner	FEP-specific pharmacotherapy via computerized decision support system
Individual Resilience Therapist	Recovery-focused education/support; integrated addictions treatment
Family Therapist	Family psychoeducation and support; communication and problem-solving
Employment/Education Specialist	Return to school or competitive work

NAVIGATE Training and Supervision

- Several in-person trainings
- Team member's guide/manual
- Site Director
  - Monthly consultation calls with the central team
- Individual Resiliency Training
  - Weekly supervision sessions with site director
  - Consultation call every two weeks with the central team
- Family Treatment
  - Consultation calls every two weeks with the central team
- Supported Employment and Education
  - Weekly supervision from site director
  - Consultation calls every two weeks with the central team

NAVIGATE Team Meetings

- Initial treatment planning meeting for NAVIGATE team, client, & relatives (within first month of enrollment)
- Treatment review & planning meeting for NAVIGATE team, client, & relatives (every 6 months)
- Weekly NAVIGATE team meeting
- Weekly supervision meeting between Director & SEE specialist
- Weekly supervision meeting between Director & IRT clinicians

Core skills of NAVIGATE team members

- Shared decision-making
- Strengths and resiliency focus
- Motivational enhancement
- Psychoeducational skills
- Collaboration with natural supports

Family Program

- Begins soon after initial contact
- Includes client, relatives, other significant persons
- Coordinated with Individual Resiliency Training
- Assessment and identification of client and family goals
- Education about disorder and treatment
- Monthly check-ins
- Family consultation
- Modified intensive skills training

Supported Education and Employment (SEE)

- Based on supported employment for severe mental illness
- Focus on helping client return to school or work
- Goals determined by client preferences
- Supports provided to help client enroll/re-enroll in school and/or obtain work
- Ongoing supports provided to maintain engagement in school or keep job
- Coordination with clinical treatment

Individual Resiliency Training (IRT)

- Flexible
- Goal oriented
- Shared decision making
- Motivation enhancement skills
- Psychoeducational skills
- Cognitive behavioral skills
- Strengths based--influence of positive psychology
- Organized into standard (recommended for all) and individualized (selected based on need and preference) modules

Implementation approach

- Initial 3-day training in Year 1 for NAVIGATE teams in central location (8-9 teams participating per training)
- 1-day booster training in Year 2 for NAVIGATE Directors
- 2-day booster training in Year 3 for all NAVIGATE teams in central location
- Biweekly group consultation calls for IRT clinicians with IRT expert, 2 teams/call
- Biweekly group consultation calls for SEE specialists with SEE expert (3-6 specialists/call)
- Weekly, then biweekly group family consultation calls for Family Program specialists with family expert
- Occasional observation of weekly team meetings, either live or in person
- Webinar trainings for new staff

Fidelity assessment

- Family Program: Certification of family clinicians based on rated audiofiles of sessions using standardized fidelity scale, followed by random selection and rating of sessions thereafter; quantitative and qualitative feedback given to clinician (2 raters)
- IRT: Same as Family Program, except 2 levels of certification corresponding to modules (Standard, Individualized); quantitative and qualitative feedback given to clinician and supervisor (3 raters)
- SEE: Adherence to defining principles of SEE based on review of contact sheets, consultant notes, administrative records (2 raters)

IRT fidelity

- 14-point scale, ranging 1 (Unsatisfactory) – 5 (Excellent) (e.g., agenda setting, cognitive behavioral therapy teaching, motivational enhancement, recovery/resiliency focus, therapeutic relationship, home assignments)
- 4/8 early sessions rated; Overall Quality $\geq$ 3 (Satisfactory) on all 4 sessions = Certification in Standard modules
- If 1 or more sessions < 3, additional sessions rated until 4/5 $\geq$ 3 = Certification in Standard
- Same criteria as above for Certification in Individualized modules

IRT fidelity Results

- 43 clinicians trained at 17 sites (range 1-4)
- 35 clinicians certified in Standard modules; at least 1 clinician per site
- Mean of 5.17 sessions to achieve Certification in Standard modules (range: 4-11)
- 14 clinicians certified in Individualized modules; at least 1 at 11/17 sites
- Mean of 4.29 sessions to achieve Certification in Individualized modules (range: 4-6)
- Ongoing monitoring of fidelity indicated maintenance of fidelity standards

Family Program fidelity

- 13-point scale, ranging 1 (Unsatisfactory) – 5 (Excellent) (e.g., agenda setting, educational strategies, motivational enhancement, problem solving recovery/resiliency focus, therapeutic relationship, home assignments)
- 4 sessions rated within first 8-12 sessions for two families; Overall Quality $\geq$ 3 (Satisfactory) on 8 sessions = Certification in Family Program
- If 1 or more sessions < 3, additional sessions rated until 8 sessions $\geq$ 3 = Certification in Family Program

Family fidelity Results

- 29 clinicians received some training
- 19 clinicians certified in Family Program; at least 1 clinician at 15/17 sites
- Mean of 9.63 sessions to achieve Certification in Standard modules (range: 8-18)
- Most common reasons for clinicians not getting certified:
  - Didn't see enough families
  - Clinician left agency

SEE Fidelity

- 9 items, each rated on 4-point, behaviorally anchored scale
- Fidelity based on principles of Individual Placement and Support, adapted for SEE and first episode psychosis population
- Ratings based on overall project period
- Specific dimensions of fidelity:
  - Frequency of contacts with SEE Specialist
  - Exclusive focus of SEE Specialist on work/school
  - Weekly supervision of SEE Specialist by Director
  - SEE Specialist participates in weekly NAVIGATE team meetings

SEE Fidelity

- Specific dimensions of fidelity: *(cont.)*
  - All clients meet with SEE Specialist
  - Focus on rapid competitive employment or integrated school search
  - SEE services provided in the community
  - Follow-along supports provided after clients obtained work or enrolled in school
  - Participation of SEE Specialist and Director on SEE consultation calls

SEE fidelity Results

- Average SEE Fidelity score = 28.58 (range: 20-35)
- Average score per item = 3.20
- Highest rated items: SEE specialist attended weekly NAVIGATE team meeting (4.0), specialist focus on work/school (3.64), specialist caseload size (3.58)
- Lowest rated items: services provided in community (2.23), participation of specialist and director on consultation calls (2.70)
- Overall pattern indicated good adherence to principles of SEE

The Outreach Plan: What it is and how to use it

- Plan is for target advertising & education
- Audience to be targeted
  - Referral sources
  - Public organizations
- Activities to be done
- Timeline for completion of tasks
- Evaluate the benefit

Target Audience: Referral Sources

- Mental health
  - Family physicians
  - Mental health clinics, addiction services
  - Hospitals, emergency rooms
- Educational establishments
  - College, school and university counseling
- Other public services
  - Police
- Most suitable contact

Target Audience: Public Organizations

- Goal is to convey information to the general public
- Libraries
- Community and recreation centers
- Public talks on mental health
- Most suitable contact

Education

- Informing family physicians, gatekeepers and agencies about the importance of early intervention
  - Education about early symptoms
  - Education about early detection
  - Referral

- Public education
  - Education about early symptoms
  - Education about early detection
  - Available resources

Referrals

- Streamline approach to receive referrals that fits with existing system
- How are you going to identify them?
- How many ways can referrals come in?
- What is the consultation process for potential referrals?
- Develop site specific recommendations on how to deal with different sources of referrals

Maintaining engagement: get it right at baseline

- Develop good relationship at baseline
- Clear about everything
- Be with them each step of assessment/engagement
- Demonstrate efficiency
- Added touches-age appropriate
- More tolerant – different than usual clinical care
- Demonstrated patient centered care

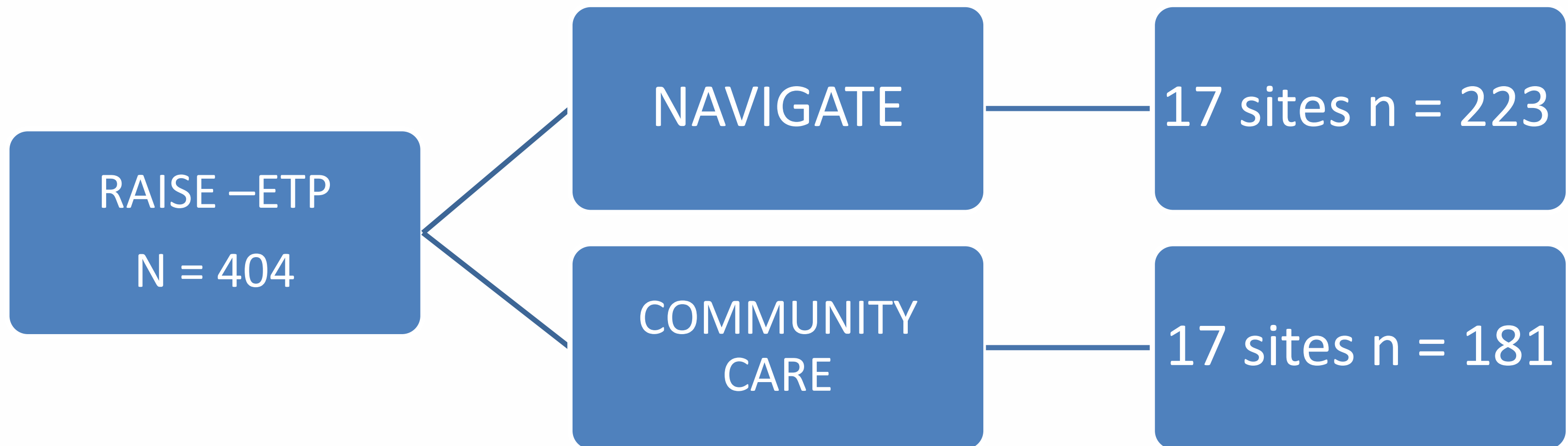
Maintaining engagement: keep it going

- Efficiency
- Know when they are coming to clinic
- Remember who they are
- Chat
- Become a friendly face around the place
- Make them feel they belong
- Reminders
- Flexible (within reason)

Randomized Controlled Trial

- NAVIGATE vs. Community Care
- Cluster/site randomization
- Two-year treatment period
- On-site recruitment and engagement
- Remote assessment of primary and secondary clinical outcomes

RAISE-ETP Study Design with Cluster/Site Randomization



Inclusion Criteria

- Age 15 – 40
- SCID confirmed diagnosis
  - Schizophrenia
  - Schizophreniform disorder
  - Schizoaffective disorder
  - Brief Psychotic disorder
  - Psychosis NOS
- No more than 6 months lifetime antipsychotic medication exposure
- First episode of psychosis

Outcome Assessments*

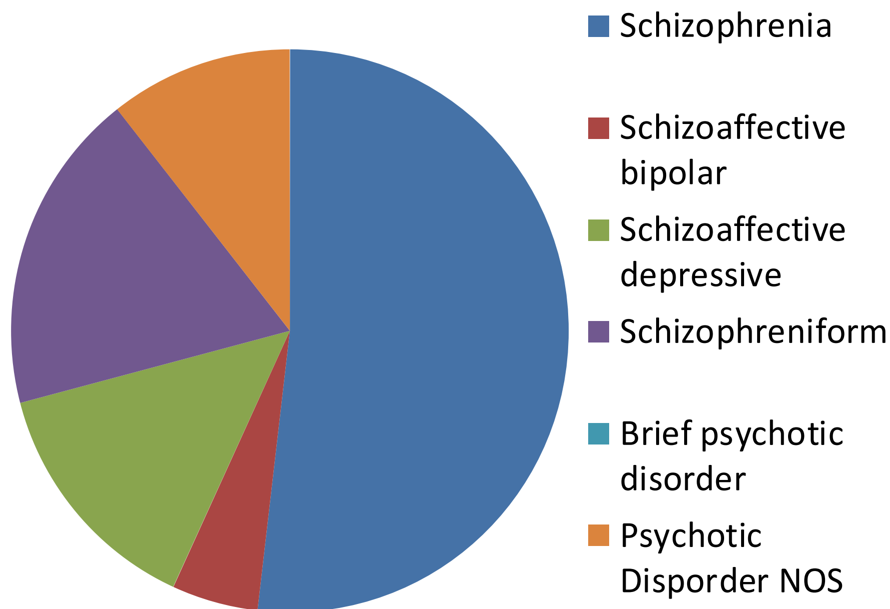
- Primary Outcome Measure
  - Heinrichs-Carpenter Quality of Life Scale
- Key Secondary Outcome Measures
  - Positive and Negative Syndrome Scale
  - Calgary Depression Rating Scale
  - Treatment received
  - School and employment activity

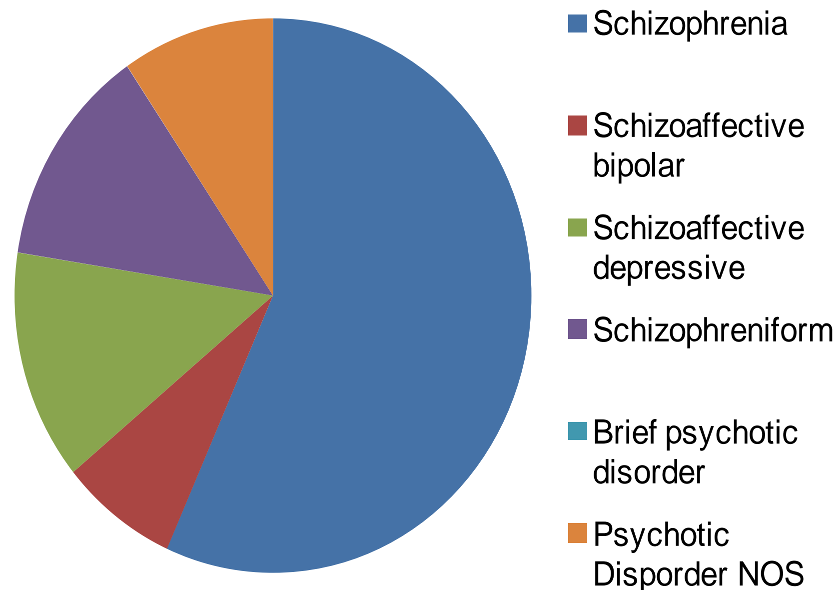
* Subset of RAISE ETP outcome measures reported February 6, 2015

Demographics
Adjusted for cluster design

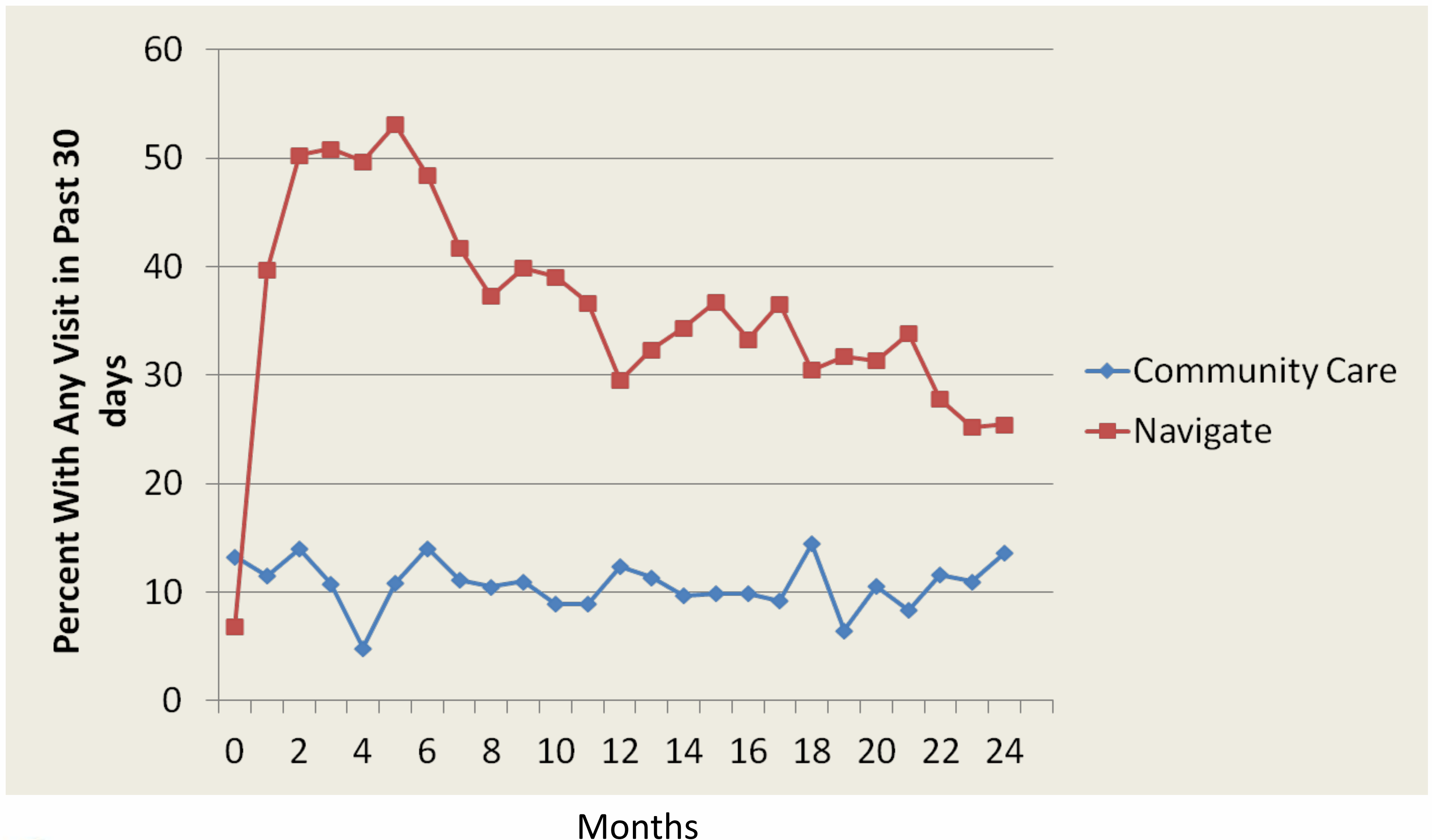
	NAVIGATE	Community Care	p-value
Age and Gender			
Age (mean)	23.5	23.2	
Males (%)	77.6	66.2	.05
Race			
White (%)	65.9	49.9	
African American (%)	25.4	44.1	
Other (%)	8.7	6.0	
Role Functioning			
In school (%)	14.9	25.5	.03
Working (%)	12.6	16.6	
Prior Hospitalization (%)	76.2	81.6	.05

Baseline Diagnoses
Adjusted for cluster design



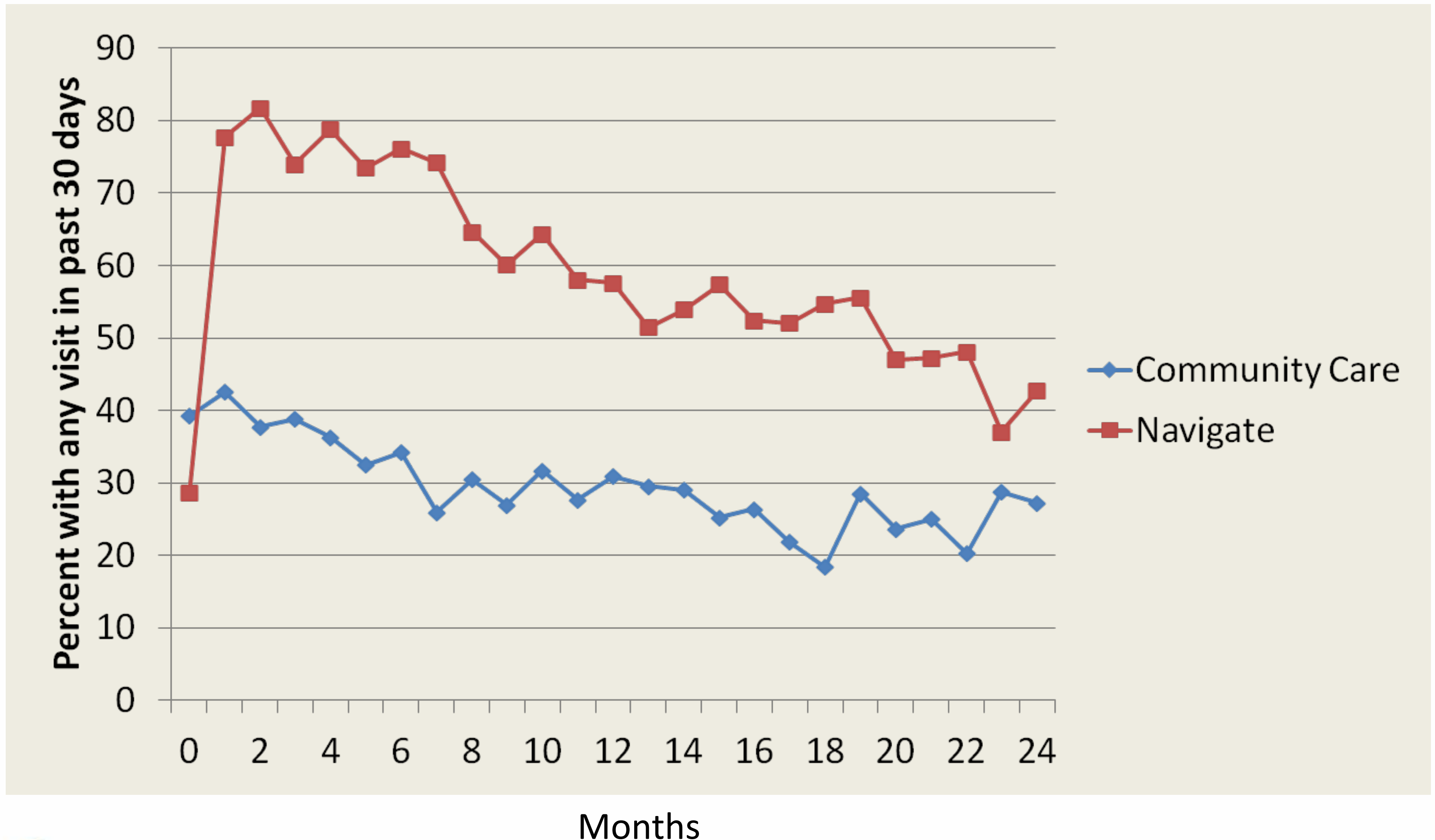


Had a Meeting About Education or Employment (% of Participants Each Month)

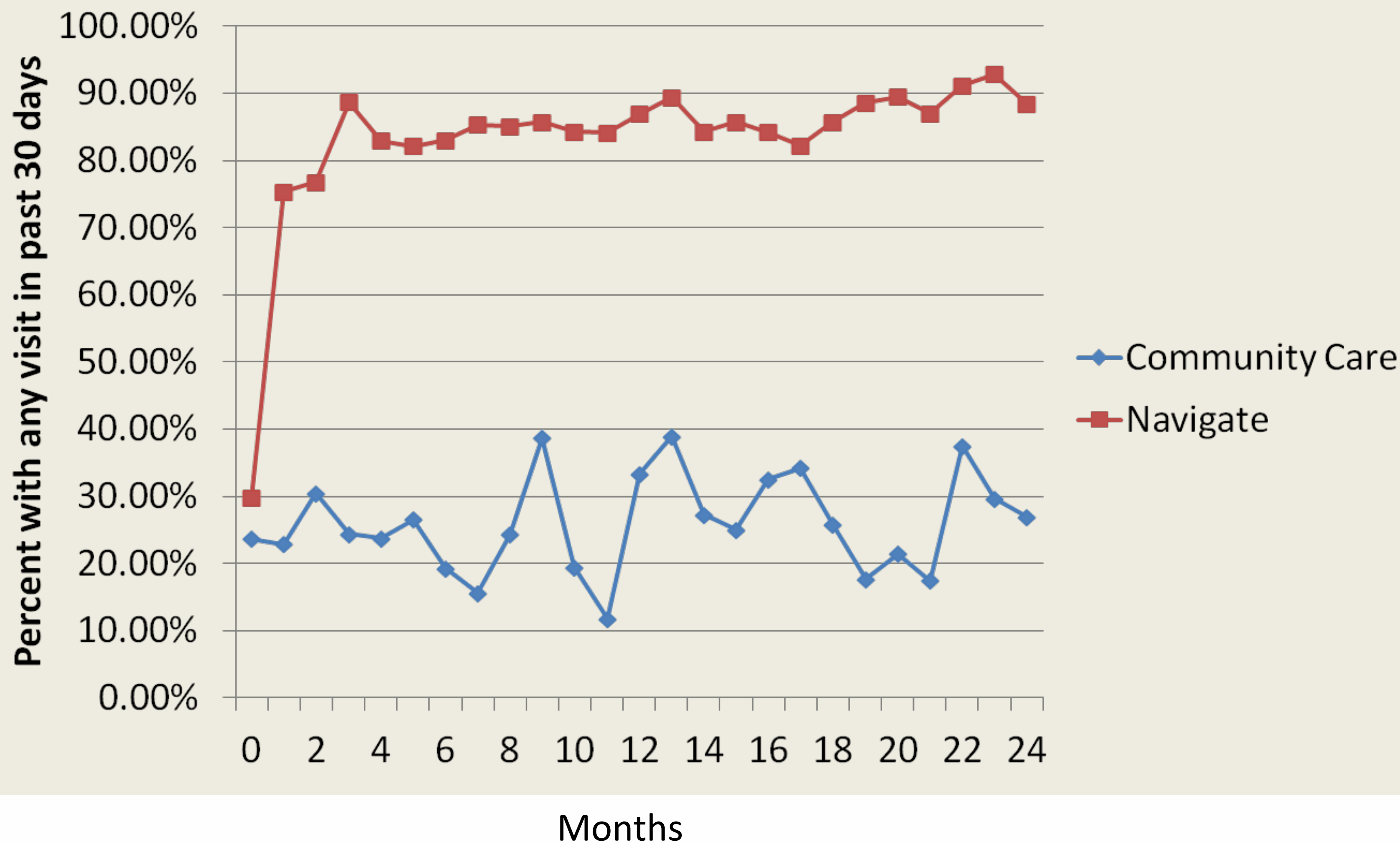


Months

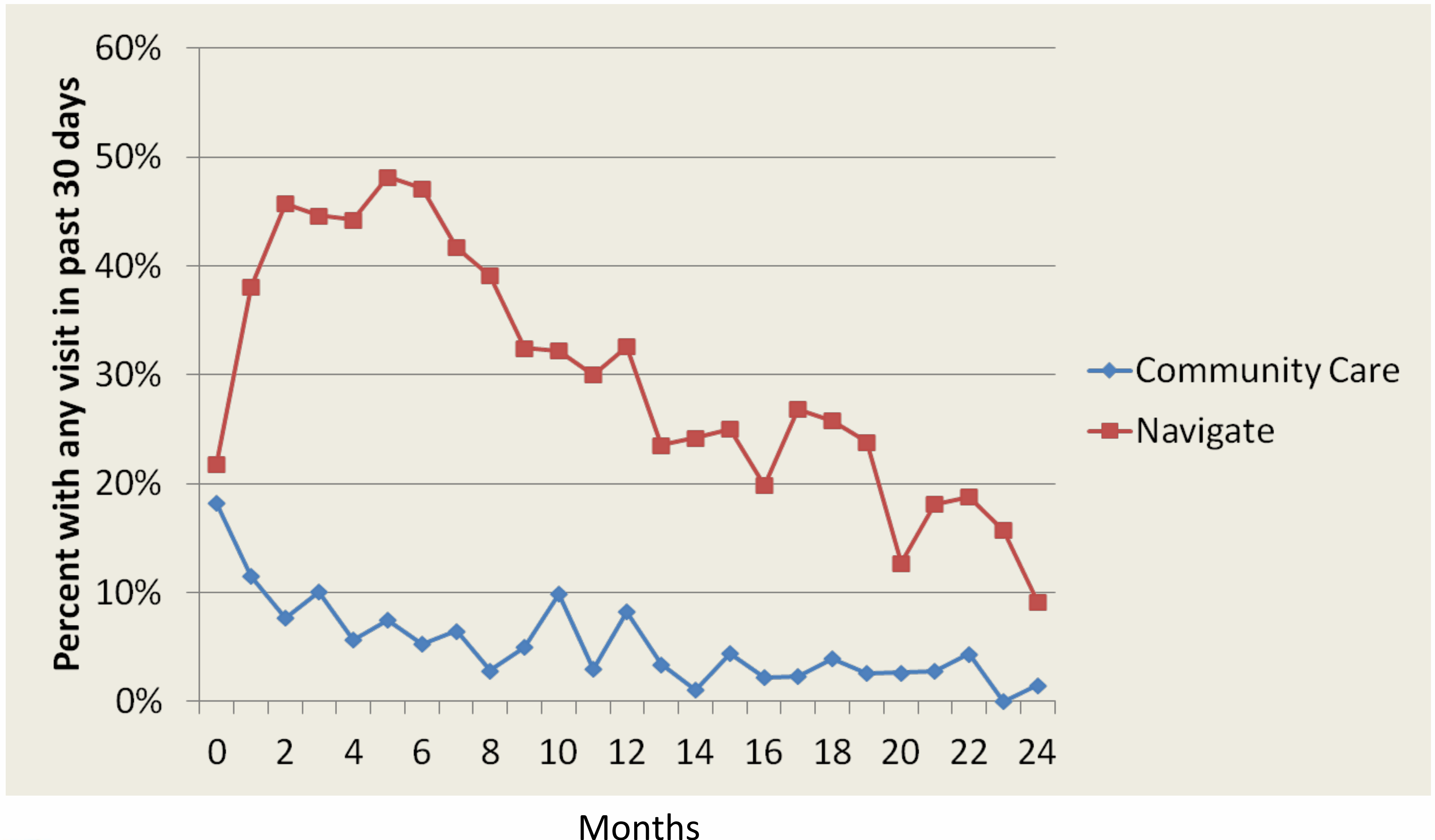
Had a Resilience-Focused Therapy Session (% of Participants Each Month)



Had a Structured Medication Assessment (% of Participants Each Month)



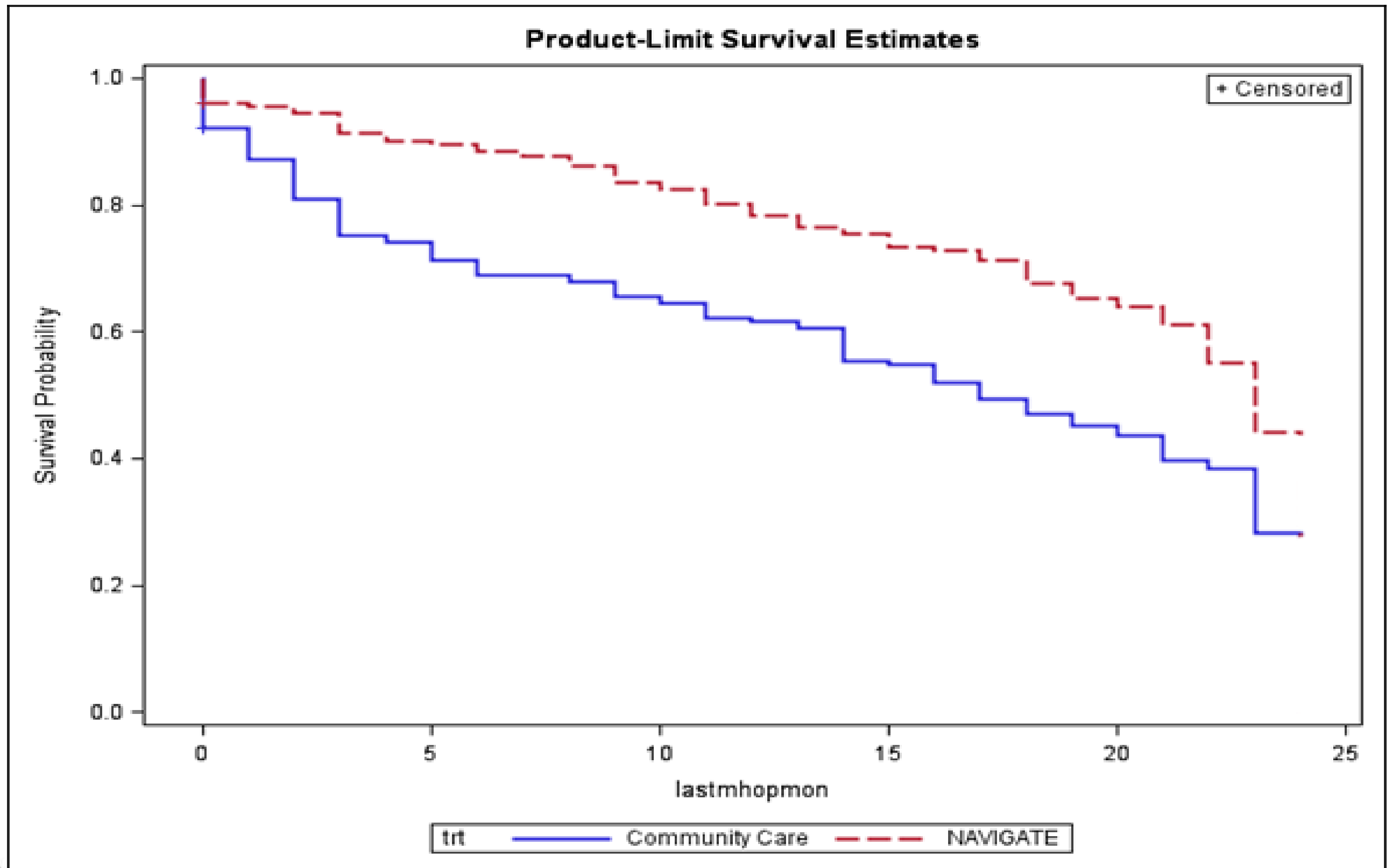
Had a Family Therapy Session (% of Participants Each Month)



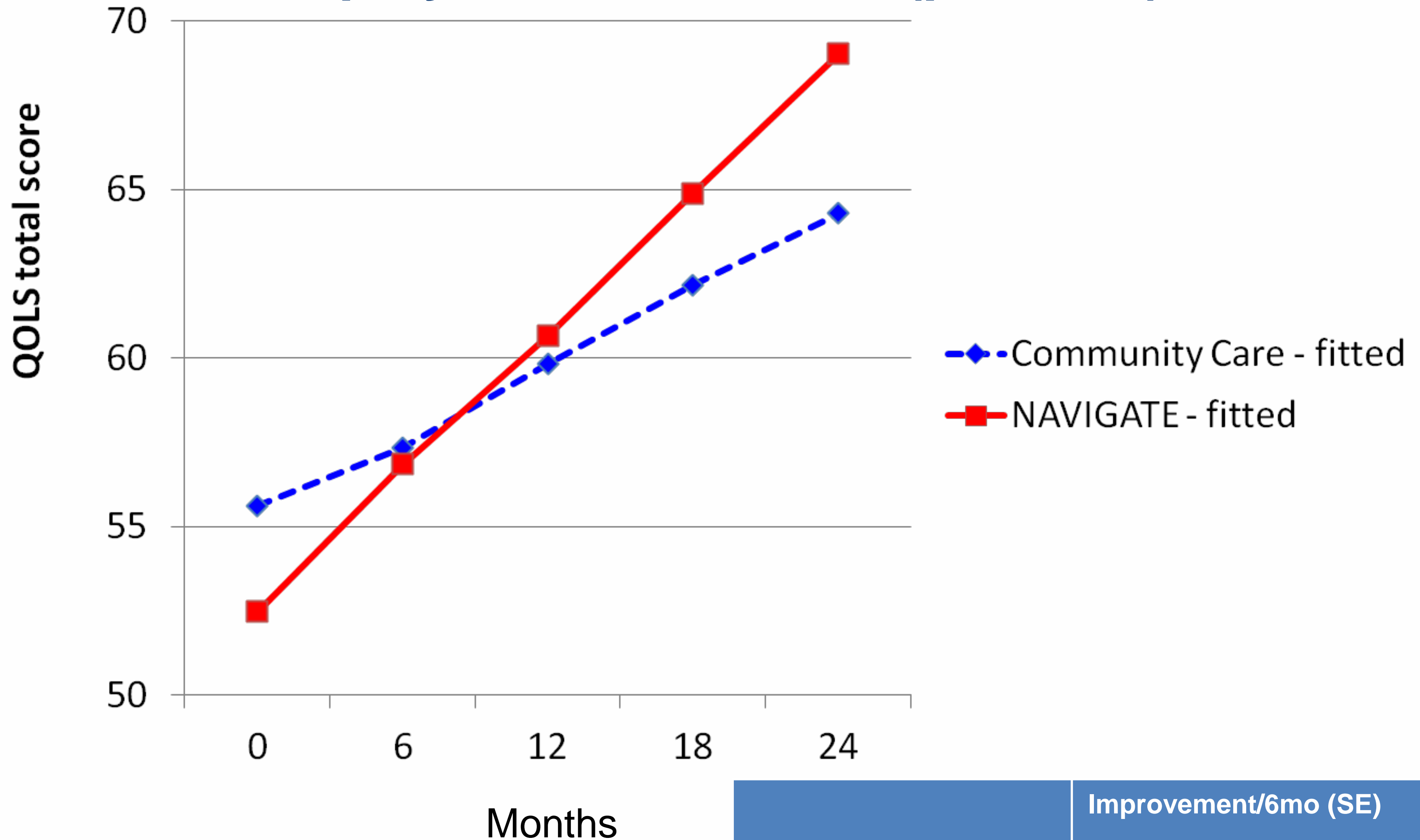
Months

NAVIGATE Participants Stayed in Treatment Longer

Time to Last Mental Health Visit
(Difference between treatments, p=0.009)



Quality of Life Scale Fitted Model
Group by time interaction (p= 0.046)

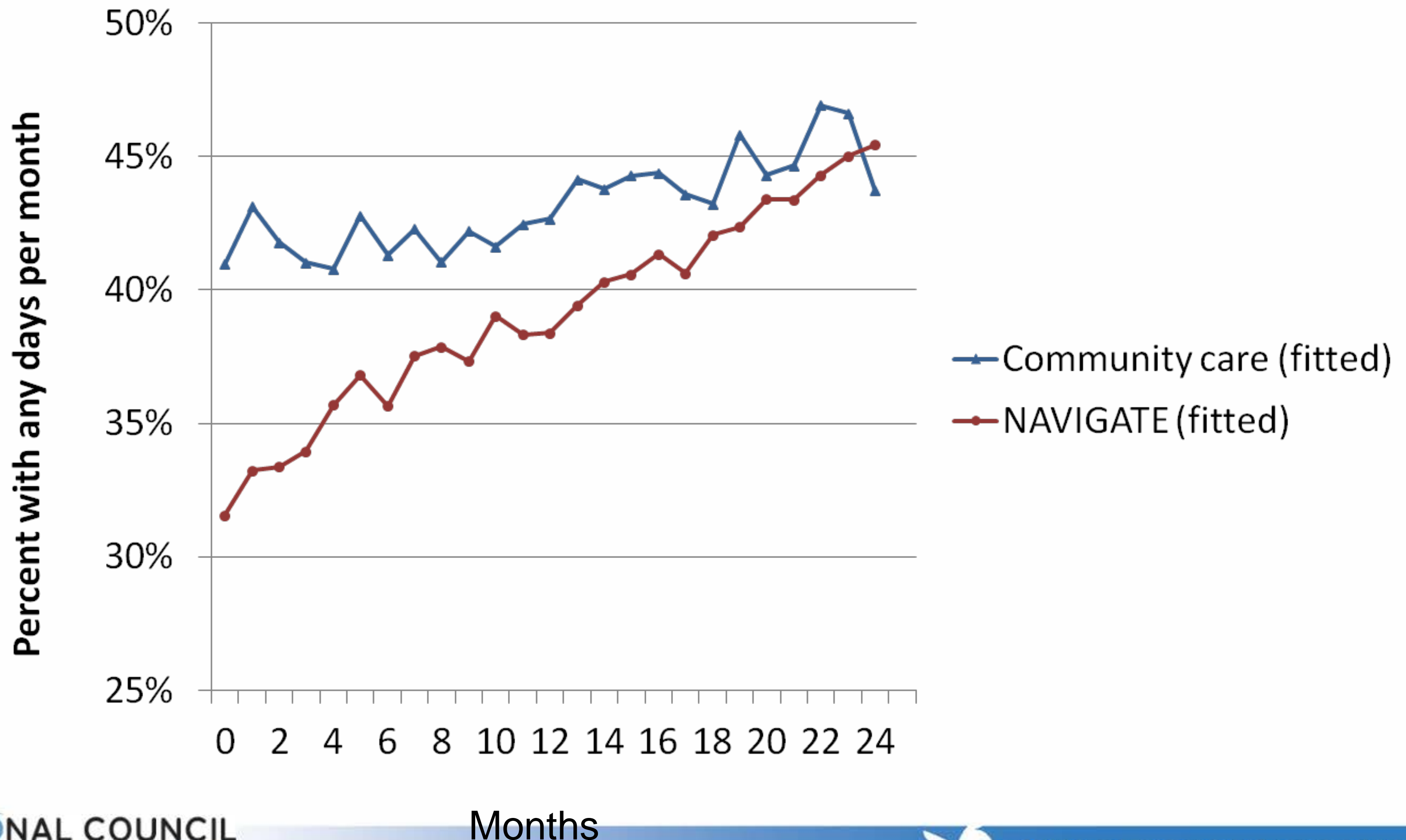


	Improvement/6mo (SE)
Community Care	2.359 (0.473)
NAVIGATE	3.565 (0.379)
Difference	1.206 (0.606)

Cohen's d = 0.257

Percent with Any Work or School Days per Month

(Group by time interaction: $p=0.044$)



Conclusions

- Recipients of NAVIGATE were significantly more likely to remain in treatment and experienced significantly greater improvement in the primary outcome measure (i.e., quality of life).
- They were more likely to be working or going to school.
- NAVIGATE participants showed a significantly greater degree of symptom improvement on PANSS and CDSS.
- DUP appears to be an important moderator of NAVIGATE effectiveness.
- These results show that a coordinated specialty care model can be implemented in a diverse range of community clinics and that the quality of life of first episode patients can be improved.

NIH National Institute of Mental Health

Transforming the understanding and treatment of mental illnesses.

SEARCH

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Coordinated Specialty Care for First Episode Psychosis - Resources

- ★ **Evidence-Based Treatments for First Episode Psychosis: Components of Coordinated Specialty Care**
- **RAISE Coordinated Specialty Care for First Episode Psychosis Manuals**
- **RAISE Early Treatment Program Manuals and Program Resources**
- ***OnTrackNY* Manuals & Program Resources**
- **Voices of Recovery Video Series**

http://www.nimh.nih.gov/health/topics/schizophrenia/raise/coordinated-specialty-care-for-first-episode-psychosis-resources.shtml

For more information about training in the NAVIGATE model, go to navigateconsultants.org, or contact Susan Gingerich, NAVIGATE Training Coordinator, at navigate.info@gmail.com.

Acknowledgements

- We are grateful to all of our core collaborators and consultants.
- We thank and acknowledge the terrific work of many clinicians, research assistants and administrators and the participating sites.
- We are very grateful for the participation of the hundreds of patients and families who made the study possible with their time, trust and commitment.